(1) For denture repair kits: Special training and tools are needed to repair dentures to fit properly. Home-repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don't fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don't fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(2) For denture reliners, pads, and cushions: Use of these preparations or devices may temporarily decrease the discomfort; however, their use will not make the denture fit properly. Special training and tools are needed to repair a denture to fit properly. Dentures that do not fit properly cause irritation and injury to the gums and faster bone loss, which is permanent and may require a completely new denture. Changes in the gums caused by dentures that do not fit properly may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(3) If the denture relining or repairing material forms a permanent bond with the denture, a warning statement to the following effect should be included: ''This reliner becomes fixed to the denture and a completely new denture may be required because of its use.''

(d) Labeling claims exaggerating the usefulness or the safety of the material or failing to disclose all facts relevant to the claims of usefulness will be regarded as false and misleading under sections 201(n) and 502(a) of the Federal Food, Drug, and Cosmetic Act.

(e) Regulatory action may be initiated with respect to any article found within the jurisdiction of the act contrary to the provisions of this policy statement after 90 days following the date of publication of this section in the FEDERAL REGISTER.

§ 801.408 Pessaries for intracervical and intrauterine use.

(a) Because of the limited evidence previously available concerning the hazards attending the use of intracervical and intrauterine pessaries, the shipment of such devices within the jurisdiction of the Federal Food, Drug, and Cosmetic Act with labeling limiting them to sale only on prescription, has not been subjected to regulatory proceedings. A recent survey shows that it is now the consensus of medical opinion among experts qualified by scientific training and experience to evaluate the safety of such devices that stem-type and wing-type intercervical and intrauterine pessaries are too dangerous for use under any form of labeling and serve no useful purpose. This opinion is particularly applicable to pessaries offered or intended for contraceptive use. These views do not apply to those pessaries, made with hollow tubes, intended solely for use when necessary to maintain drainage from the uterine cavity.

(b) On the basis of this consensus of expert opinion and the supporting evidence of many known injuries, the Food and Drug Administration concludes that stem-type and wing-type intracervical and intrauterine pessaries are dangerous to health, and regardless of their labeling, may be shown to be misbranded within the meaning of sections 502(f) (1) and (2) and 502(j) of the Federal Food, Drug, and Cosmetic Act. It is recommended that distributors of these devices remove them from the interstate market at once. Regulatory action may be instituted in connection with any such devices found within the jurisdiction of the act.

§ 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.

(a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

(b) The consensus of the ophthalmic community is that the number of eye